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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,609	09/30/2005	Darko Filic	1034433-000010 (078556-01)	4208
23524 7590 06/03/2008 FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			EXAMINER DAVIS, ZINNA NORTINGTON	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 06/03/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,609	Applicant(s) FILIC ET AL.	
	Examiner Zinna Northington Davis	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-15 are pending in the instant application.
2. After the title, at page one of the specification, the continuing data should be inserted.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

Art Unit: 1625

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Topfmeier Fritz et al, U.S. 4,743,693, Dreckmann-Behrendt et al, U.S. 6,166,045, or Rollinger et al (all references cited by Applicants).

The instantly claimed process for the preparation of modification of torasemide is disclosed. The prior art references teach the preparation of modification I of torasemide having the same chemical structure which has useful pharmacological properties.

The difference between the prior art and the claims is that the X-ray diffraction pattern of the crystalline solid of the prior art may differ from that of the X-ray diffraction pattern of the instant claims, i.e. neither U.S. patent specifically discloses a table of lattice spacing that anticipates the instant claims.

It would have been obvious to one of skill in the art to prepare the crystalline modification I as instantly claimed. Polymorphism is the existence of different solid forms (modifications) of a compound which have the same chemical composition but different structures and thus different physical and sometimes also chemical properties.

Thus, by replicating known conditions for reaching specific crystalline modification, one would always obtain the same polymorph of torasemide, i.e. in this case, crystalline modification I. The lattice spacings are an inherent property of the known "crystalline modification I of torasemide," and are not a distinguishing characteristic per se. Furthermore, mere difference in physical

Art Unit: 1625

property is well known conventional variation for the same pure substance which makes the modification prima facie obvious.

One would be motivated to prepare the instantly claimed invention since the prior art references have taught the preparation of the known crystalline form I.

To overcome this rejection, it is suggested that the novel physical characteristics of the modification 1 of torasemide obtained by the claimed process should be incorporated into the claims.

7. The Information Disclosure Statement filed September 30, 2005 has been considered.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682. The examiner can normally be reached on M-F.
9. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

Art Unit: 1625

Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zinna Northington Davis/
Zinna Northington Davis
Primary Examiner
Art Unit 1625

Znd
05.21.2008